



21 August 2013
EMA/PRAC/751078/2012 Rev.2

Timetable for the procedure

Referral under article 31 of Directive 2001/83/EC resulting from pharmacovigilance data

Hydroxyethyl starch containing medicinal products, solution for infusion

Procedure no: EMEA/H/A-31/1348

Procedural step	Date
Notification:	20 November 2012
Start of the procedure (PRAC):	December 2012 PRAC (26-29 November 2012)
List of Questions (LoQ):	29 November 2012
Submission of responses:	04 February 2013
Re-start of the procedure:	11 February 2013
Rapporteur and Co-rapporteur assessment report(s) circulated to PRAC and to CMDh ¹ :	08 April 2013
Ad hoc expert group meeting:	19 April 2013
Comments:	22 April 2013
Updated Rapporteur and Co-rapporteur assessment report(s) circulated to PRAC and to CMDh:	03 May 2013
PRAC List of Outstanding Issues (LoOIs) to be addressed in an Oral Explanation:	16 May 2013

¹ Co-ordination Group for Mutual Recognition & Decentralised Procedures – Human



Oral Explanation and PRAC recommendation to CMDh:	June 2013 PRAC (10 – 13 June 2013)
Re-examination - receipt of letter of intent from MAH by:	10 July 2013
Re-examination - Receipt of detailed grounds from MAHs:	19 August 2013
Re-examination - Start of re-examination procedure:	20 August 2013
Re-examination - Rapporteur assessment report and Co-rapporteur assessment report circulated to PRAC and to CMDh:	9 September 2013
Re-examination – Ad hoc expert meeting:	13 September 2013
Re-examination - Comments:	16 September 2013
Re-examination – Updated rapporteur assessment report and Updated co-rapporteur assessment report circulated to PRAC and to CMDh: :	26 September 2013
Re-examination - Oral explanation/PRAC final recommendation to CMDh:	October 2013 PRAC (7 – 10 October 2013)